



## **I. Policy**

- A.** No human research will be initiated without prospective IRB review and approval.

### **B. Required Elements**

The protocol submitted to the IRB must include all elements from the MUSC protocol template. The protocol format is:

1. Objectives/specific aims,
2. Background,
3. Intervention to be studied (if applicable),
4. Study Endpoints (if applicable),
5. Inclusion and Exclusion Criteria/ Study Population,
6. Number of Subjects,
7. Setting,
8. Recruitment Methods,
9. Consent Process
10. Study Design / Methods
11. Specimen Collection and Banking (if applicable)
12. Data Management
13. Provisions to Monitor the Data to Ensure the Safety of Subjects (if applicable)
14. Withdrawal of Subjects (if applicable)
15. Risks to Subjects
16. Potential Benefits to Subjects of Others
17. Sharing of Results with Subjects
18. Drugs or Devices (if applicable)

### **C. FDA Regulated Products**

All studies involving FDA regulated products will be reviewed and approved in accordance with FDA regulations.

### **D. Memorandum of Understanding**

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H.

Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards”.

## **II. Procedures**

### **A. Submission by the Principal Investigator**

The Principal Investigator submits the protocol for “Full IRB Review”, ensures relevant information (including Conflict of Interest) has been completed and documentation appropriate to the study has been uploaded. In performing this submission, the Principal Investigator electronically signs the Principal Statement of Assurance Form.

### **B. The submission will automatically be routed to appropriate departments following HRPP Program Guide 1.7.**

### **C. Processing by IRB Administration**

- 1) Upon receipt of an application, the application is checked by the IRB staff for completeness. If additional items are necessary to complete the submission, the IRB staff will note the items and return the study to the Principal Investigator/study communication coordinator leads in eIRB.
- 2) When the IRB receives an application that is prepared in such a way that the proposed research procedures are unclear or large components of the application are missing, reviewers will be unable to provide meaningful comments and guidance. In such cases, the application will be returned to the PI with the status of Not Ready for Review, and recommendations for additional resources and guidance will be provided to the PI.
- 3) Study personnel listed on the application are checked against the Compliance Office database to ensure required institutional training has been completed. If not all personnel have completed training, the PI/ study communication coordinator leads in eIRB. is notified that that IRB approval of the study will not be released until documentation that all study personnel have completed required education is received in the IRB office.
- 4) The IRB Administrator administratively reviews the eIRB application for regulatory compliance and adherence to established guidelines.

### **D. Assignment of Reviewer**

1. The IRB Administrator will assign initial protocols to primary reviewers.
  - a) Each Primary Review Group will include someone with the relevant expertise and knowledge is included to conduct an in depth review.
  - b) No Board member who may have a conflict of interest is assigned to a study as primary reviewer.
2. If an IRB member notifies the Administrator that he/she does not feel competent to review a protocol/amendment assigned, the material will be reassigned.
3. The IRB Administrator will ensure the prisoner representative is a primary reviewer for any initial protocols involving prisoners and is a reviewer for any amendments and continuation applications for protocols involving prisoners; the prisoner representative will be a voting member of the convened meeting where these documents are discussed.

#### **E. Use of Non-IRB Members with Expertise**

1. The IRB Administrator, chair, and/or any voting member may request additional expertise when reviewing a protocol.
2. The chair or designee will contact an individual with the expertise requested.
3. The required expertise will be sought among the MUSC faculty if available and without a conflict of interest.
4. The chair or designee will indicate the concerns/questions requiring expert review.
5. The IRB Administrator will ensure the expert has all the materials required to review and address the concerns/questions.
6. Depending on the request and need for the additional expertise, the chair will ask the expert(s) to discuss concerns/questions with a Board member, document his/her review, and/or attend the relevant convened Board meeting.

#### **F. Review Material for IRB Members**

1. The complete application is available to all IRB members through the eIRB system. The IRB Administrator will select the primary reviewers and upload the appropriate IRB reviewers' checklists. The eIRB system

will send a review request to the primary reviewers containing a link to the protocol in the eIRB system. The application consists of the following items when applicable to the study:

- a) Study Application Smartforms,
- b) Study protocol,
- c) Investigator drug brochures,
- d) The consent documents or waivers of consent documents,
- e) HIPAA or HIPAA waiver document,
- f) Advertisements,
- g) Questionnaires and Surveys,
- h) Conflict of Interest Disclosure, and
- i) Drug and/or Device smartforms.

2. The checklists received by the primary reviewers for assessment to ensure consistency and completeness are (as appropriate to the specific study):

- a) IRB Reviewer Checklist (Full Board Review)
- b) Informed Consent Document Checklist
- c) Special Subject Populations Checklist if applicable
  - 1) Children
  - 2) Cognitively Impaired or Persons Unable to Consent
  - 3) Pregnant Women, Fetuses, Neonates
  - 4) Prisoners
  - 5) If applicable, checklist addenda for Department of Defense, Department of Education, Department of Energy, Department of Justice, Environmental Protection Agency.

3. The IRB Administrator sends the agenda to selected IRB members. IRB members receive an email to link to the agenda of the protocols under initial review for the scheduled meeting.

4. The application submission is generally assigned 3 weeks prior to the next scheduled Board meeting.

**G. Review Criteria** - The primary reviewers are assigned to assess the following:

1. risks to the subjects have been minimized by using sound research design, and, whenever appropriate, using procedures already being performed on the subject for diagnostic or treatment purposes,
2. risks, including physical, psychological, social and economic risks, are reasonable relative to anticipated benefits,
3. selection of subjects is equitable,
4. the informed consent process and document are in compliance with MUSC policies and federal regulations,

5. provisions are adequate to protect the privacy of subjects and confidentiality of data,
6. if the research subjects include a vulnerable group, additional safeguards have been included to protect the rights and welfare of these subjects and that all special requirements for the populations have been adequately addressed, and
7. the recommended frequency of continuing review.

#### **H. Documentation of Primary Review**

1. Using the designated review procedure, the primary reviewer enters reviewer comments.
2. The Administrator requests the reviewers' critiques by a stated deadline.
3. The primary reviewers finalize their reviews by categorizing their recommendation as approval, conditional approval, or disapproval and summarize the suggested modifications that may be required for the study to achieve an acceptable benefit/risk ratio.
4. The IRB staff summarizes the reviewers' comments and discusses these comments with the reviewers and IRB Chair as necessary for clarification.

#### **I. Communication between IRB Administration and PI prior to meeting**

1. The IRB staff sends all comments to the study communication leads electronically. A date of when their response is due is given based on when the comments were received.
2. The IRB Administrator checks the study team's response and marks the changes to correspond with the comments and uploads the response with the agenda for the Board's review.
3. The IRB Chair reviews the Principal Investigator's response and seeks additional information from reviewers and/or the Principal Investigator when necessary to clarify issues/concerns.
4. Principal Investigator responses that come in after the agenda has been sent out will be reviewed by the Chair when possible to determine if additional information would be useful; all complete investigator responses will be presented to the Board at the meeting.

#### **J. Convened IRB**

1. During the Board meeting, each initial study is presented by the Chair and/or Primary Reviewer(s), discussed and voted on individually. The

Principal Investigator will be present if requested by any Board member or if the Chair/Administrator thinks the Investigator needs to be present to clarify issues/concerns.

2. The Board may approve, table, disapprove, or require modifications to secure approval. If the Board requests minor modifications which do not substantially impact the risk/benefit analysis, the Board may approve the study contingent on final review and approval by the Chair or the Chair's Designee. No required changes to the informed consent document will be deferred to the Chair's or Chair's Designee approval unless the Board has stipulated the wording of these changes. Changes that are substantive in nature will result in the study being tabled and must be brought back to the Full Board at a convened meeting for approval.

#### **K. Communication between the Institutional Review Board and the Office of Research and Sponsored Programs**

If the study is sponsored by a Corporate or Industry sponsor, the Approval form and Informed Consent are reviewed by the Office of Research and Sponsored Programs. ORSP will review the approved consent sponsor commitment language against the sponsor/MUSC contract and notify the Administrator by email once the contract negotiations are complete and the study can be released

#### **L. Post-IRB Communication with the PI**

1. For approved studies, the IRB administrator completes the following activities:
  - a) The informed consent(s) is/are electronically stamped with the approval date.
  - b) The HIPAA Authorization and advertisements are electronically stamped with the approval date.
  - c) An approval letter is prepared. This letter includes the following:  
**Electronic Signature:** *This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*
  - d) The approval is electronically issued in the system.
2. For studies requiring modification, the IRB administrator completes the following activities:
  - a) The IRB reviewers' comments and requirements are summarized.

- b) A letter from the Chair or Chair's Designee notifying the PI/study team that the IRB requires changes to the study is prepared.
  - c) The letter is sent to all study communication leads.
- 3. If the Board Tables the study, the IRB Administrator completes the following activities:
  - a) The IRB reviewer's comments and requirements are summarized.
  - b) A letter from the Chair or Chair's Designee notifying the PI/Study team that the IRB has tabled the study is prepared.
  - c) The letter is sent to all study communication leads.
  - d) The PI may be invited to attend the next meeting.
- 4. If the Board disapproves the study, the IRB Administrator completes the following activities:
  - a) The IRB reviewers' comments and requirements are summarized.
  - b) A letter from the Chair or Chair's Designee notifying the PI/study team that the IRB has disapproved the study is prepared.
  - c) The letter is sent to all study communication leads.
- 5. For changes submitted by the study team in response to IRB request:
  - a) If the study modifications are minor in nature, the IRB Administrator will forward to the Chair or the Chair's designee for review.
    - 1) If the Chair finds the modifications acceptable, the Chair will indicate approval and the IRB Administrator will complete the steps in **L.1** above.
    - 2) If the Chair determines additional modification are necessary, the Chair will indicate changes required and the IRB Administrator will complete the steps in **L.2** above.
  - b) Study Team responses to substantive modifications due to being tabled or disapproval are presented to the Full Board for review, discussion and vote at a convened meeting.
- 6. If a study has been disapproved and a Principal Investigator has appealed the Board's decision in writing to the Chair, the Administrator will place the

item on the next available agenda for full Board discussion and vote. The Principal Investigator will be notified of the date, time and place of the meeting.

#### **M. Duration of Approval**

1. Unless renewed, a protocol is active for one year. The expiration date, the last day the protocol is approved, is calculated as no more than 365 days after approval. The calculation of the approval period is based on the date of the convened meeting at which the IRB approves the protocol and not on the date when the reviewer approves any requested modifications.
2. For all approved research protocols, the IRB may determine that the research risk is of significant magnitude meriting review more frequently than on an annual basis.